REMARKS

Claims 1-4, 6, 10 and 12 are amended herein. Claims 5, 7-9 and 11 are canceled. New claims 13-17 are added. Support is found, for example in the original claims, pages 19-24 and the working examples.

No new matter is presented.

I. Response to Claim Rejections Under 35 U.S.C. § 112

Claims 1-12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

(1). Regarding claims 1-8 and 10-12, the Examiner asserts that the term "for using solid formulation" is vague and indefinite.

(2). Regarding claims 1-9, the Examiner asserts that the term "a range showing no influence on product stability" is vague and indefinite.

With respect to paragraph (1) above, the claims have been amended to recite "for using a solid formulation", thereby clarifying the claim language and obviating this ground for rejection.

With respect to paragraph (2) above, the phrase, "a range showing no influence on product stability" has been deleted, thereby obviating this ground for rejection.

Accordingly, Applicants respectfully request withdrawal of the § 112, second paragraph, rejection.

II. Response to Obviousness-Type Double Patenting Rejection

In paragraph 5 of the Action, claims 1-12 are rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over the claims 1-13 of the Umejima et al (US 2008/0103171).

Applicants defer responding to the rejection and respectfully request that the rejection be held in abeyance.

III. Response to Claim Rejections Under 35 U.S.C. § 102

In paragraph 6 of the Action, claims 1-12 are rejected under 35 U.S.C. § 102(e) as being anticipated by Slatter (US 2004/0138253).

Applicants respectfully traverse the rejection.

Slatter discloses a quaternary ammonium compound having an effect as an antimuscarinic agent and discloses all sterecisomers thereof.

Slatter discloses a method which uses this compound for the treatment of asthma, chronic obstructive pulmonary disorder, allergic rhinitis, and infectious rhinitis.

Slatter does not disclose, teach or suggest the existence of amorphous solifenacin or the process of preparing a composition of solifenacin or a salt thereof for use in a solid formulation. Thus, for at least this reason, Slatter does not anticipate the present invention.

Even further, the technical object of Slatter and the means for solving the problem are different from the present invention which is to provide a stable pharmaceutical composition. Thus, there is no apparent reason for one of ordinary skill in the art to modify the disclosure of Slatter with a reasonable expectation of success. For this additional reason, the present invention is patentable over Slatter.

In paragraph 7 of the Action, claims 1-12 are rejected under 35 U.S.C. § 102(e) as being anticipated by Fraser et al (US 2004/0198822) (hereinafter Fraser et al).

Fraser et al discloses a method for using an $\alpha_2\delta$ subunit calcium channel modulator and a compound having smooth muscle modulatory effects to increase effectiveness and lower the side effects.

Solifenacin, which is a antimuscarinic agent, is disclosed as a smooth muscle modulating factor.

Fraser et al does not disclose, teach or suggest the existence of amorphous solifenacin. or the process of preparing a composition of solifenacin or a salt thereof for use in a solid formulation. Thus, for at least this reason, Fraser et al does not anticipate the present invention.

Even further, the technical object of Fraser et al and the means for solving the problem are different from the present invention which is to provide a stable pharmaceutical composition. Thus, there is no apparent reason for one of ordinary skill in the art to modify the disclosure of Fraser et al with a reasonable expectation of success. For this additional reason, the present invention is patentable over Fraser et al.

In paragraph 8 of the Action, claims 1-12 are rejected under 35 U.S.C. § 102(e) as being anticipated by Saito et al (US 2005/0181031).

Saito et al discloses an invention relating to a method for enhancing the transdermal permeation of a solifenacin transdermal preparation.

Saito et al describes that a fatty acid ester, which is a transdermal permeation enhancer, specifically achieves this effect.

Saito et al neither discloses, teaches nor suggests the existence of amorphous solifenacin. Thus, for at least this reason, Saito et al does not anticipate the present invention.

Even further, the technical object of Saito et al and the means for solving the problem are different from the present invention which is to provide a stable pharmaceutical composition. Thus, there is no apparent reason for one of ordinary skill in the art to modify the disclosure of Saito et al with a reasonable expectation of success. For this additional reason, the present invention is patentable over Saito et al.

In summary, none of the references teaches or suggests the existence of amorphous solifenacin. The technical object and the means for solving the problem of the cited references are different from the present invention which is to provide a stable pharmaceutical composition. Accordingly, the invention of amended claim 1 is both novel and non-obvious. Claims 2-12 depend directly, or indirectly from claim 1 and are patentable for at least the same reasons.

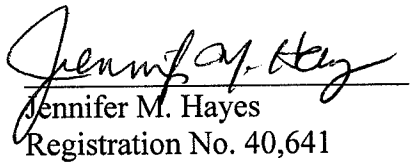
Accordingly, Applicants respectfully request withdrawal of the prior art rejections.

IV. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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